8EHQ-1201-15032 53504

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SASOL

December 18, 2001

Document Processing Center (TS-7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

ATTN: 8(e) Coordinator

Contain NO CBI

Subject: Section 8(e) Submission

Dear Sir or Madam:

This submission is provided on behalf of Sasol North America Inc. (Sasol NA) in accordance with section 8(e) of the Toxic Substances Control Act. It presents the results of a Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Tests (OECD 422) conducted on LINPAR 10 (97% 1-decane). This study was performed in support of the assessment of 1-decane (CAS no. 124-18-5) being conducted under the sponsorship of Italy in the OECD SIDS program. Sasol NA was only recently had aware of its results as part of a data gathering exercise. The details of this study and its findings are provided in the enclosed report and are summarized below.

Test Methods

The test substance was administered orally by gavage to Crl: CD (SD) BR male and female rats which were divided into four treatment groups of 10 animals/sex/ group and treated daily at doses of 0, 25, 150 and 1,000 mg/kg. Females were treated for 14 days prior to mating through day 4 of lactation. Males were treated for 14 days prior to mating, during mating until the end of the mating period. The animals were observed daily for clinical signs and mortality. Individual body weight and food consumption was recorded. The dams reared their young until day 4 of lactation. Functional tests (startle reflex, grip reflex and an open field evaluation) were performed on 5 animals/sex/group the day before sacrifice. Hematological examinations and blood chemistry tests were performed on 5 animals/sex/group at sacrifice. Urinalysis was also conducted on the males that were selected for hematological evaluation. Gross necropsies were conducted and the reproductive organs of both sexes were weighed. The number of implantation sites were recorded. Histopathological examinations were conducted on organs of the control and high dose group.

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Results and discussion:

The results for this study are largely unremarkable. No clinical signs, behavioral changes or deaths were found at any dosage. No effect on the mating index was observed. No treatment-related changes were seen in the organ weights of both sexes. No significant different in mean body weight and daily food consumption was noted. No effects were observed on parturition, postnatal survival, and mean pup weights or in any of the functional tests. No significant urological findings were noted (analysis limited to males only).

The fertility index was lower in the exposed animals versus the controls, but this difference was not dose-related. Given the lack of a dose-related pattern of response, as well as any evidence of histopathology of reproductive organs, it does not appear likely that this effect is directly related to the toxicity of the test substance itself.

A slight, non-statistically significant increase in mating time that was within the normal range of variability for this train of rats was observed in the high dose group only.

There was a trend toward increased SGPT activity in test substance exposed females, but this was not dose-related or statistically significant. In females, there was also a trend toward increased cholesterol, but the increase was not statistically significant.

Necroscopic examination revealed test-substance related thickening of the non-glandular mucosa sometimes associated with slight erosion of the non-glandular mucosa and/or with thickening of the cuticular ridge of the stomachs of both sexes. These changes were present in the high and middle dose group and only a few of the animals in the low dose group. These findings were confirmed by histological examination in which hyperplasia of the non-glandular mucosa, associated in most cases with degeneration, hyperkeratosis and submucosal subacute inflammation were seen. These changes were dose-related in degree and frequency. While these effects are appear to be treatment related they are considered a likely artifact due to the manner in which the test substance is delivered to the test animals and not applicable to the manner in which humans would be exposed.

Exposure Controls/ Personal protection

This study should not raise concerns regarding the continued commercial use of this substance. Sasol NA does not manufacture and sell decane per se; however, it is a component of products the company produces. Under normal industrial manufacture and end-use conditions there is little or no potential for significant human exposure to decane. When contact with liquid product is

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possible, use of face shield and or chemical splash goggles is recommended to protect the eyes, otherwise safety glasses with side shields or goggles may be used. Chemical gloves should be worn to prevent repeated contact with skin. If skin exposure is anticipated, use full protective clothing and chemical boots. Mechanical ventilation is also recommended if handling the material in enclosed spaces or at elevated temperatures. In cases where additional respiratory protection is required, it is recommended workers use NIOSH-approved organic vapor air-purifying respirators, self-contained breathing apparatus, or air-supplied respirators dependent on concentration.

Products containing decane are used as reaction intermediates, such as in the production of chlorinated paraffins, oxidation to alcohols, nitration to nitro-alkanes and amines, sulfoxidation or sulfochlorination for surfactant or plasticizer manufacture and as raw materials for microbiological oxidation and fermentation processes. Because decane is destroyed in these reactions there is very limited potential for significant human exposure in these applications. Sasol NA does find direct use of some of its decane-containing products as solvents. While exposure may be possible with such uses, the results of this study suggest a low likelihood for any significant toxicological effects.

As indicated above, both the results of this study and the anticipated use patterns do not present any significant health concern associated with continued manufacture and use of this substance.

Any questions about this submission should be directed to the undersigned as indicated.

Respectfully submitted,

Dave Penney

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